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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,752

Applicant(s)

AKIMOTO, TAIZO

Examiner

Jeanine A. Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,10,11 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,8,10,11 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed September 12, 2006. Currently, claims 7-8, 10-11, 18-22 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 8, 11, 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiraishi et al. (US Pat. 4,617,468, October 14, 1986).

Given the clear decision by the Board of Appeals on September 27, 2005, the “means for obtaining information concerning the positions of the probes to which the

target substance has bound and simultaneously detecting the management information attached to the test piece” has been defined by the decision and the specification as a “stimulable phosphor sheet” (see page 6 of the decision).

In *Re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held: The plain and unambiguous meaning of paragraph six is that one construing means- plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure.

Shiraishi et al. (herein referred to as Shiraishi) teaches a stimulable phosphor sheet with hydrophilic surface. Shiraishi teaches an analysis system comprising an electrophoretic gel (means for attaching management information peculiar to the test piece to a predetermined location on the test piece using a marker the same as or similar to the marker used for marking the target substance), a stimulable phosphor sheet (means for obtaining information concerning the positions of the probes to which the target substance has bound and simultaneously detecting the management information attached to the test piece), and the stimulable phosphor sheet (means for storing the management information in association with the information concerning the positions of the probes to which the target substance has bound). Specifically, Shiraishi illustrates, in Figure 1 an example of a read-out system for reading out the locational information of the radioactively labeled substances copied and stored in a stimulable phosphor sheet (col. 6, lines 25-35). Shiraishi teaches that radioactively labeled

substances originating from an organism include polymeric substances such as proteins, nucleic acids, derivatives thereof or cleavage products thereof provided with a radioactive label (col. 13, lines 25-35). Shiraishi teaches the labeled substance may be resolved using support mediums such as electrophoresis. Therefore, Shiraishi teaches electrophoresis as a means for attaching the labeled substances to the test piece.

Shiraishi teaches the read-out procedure of the autoradiograph copied and stored in the stimuable phosphor sheet can be done in the composite form containing the support medium or after removing the support medium therefrom (col. 14, lines 34-45).

Therefore Shiraishi teaches that the stimuable phosphor sheet is a means for obtaining information about positions of the probes, but also a means for storing the information with the information concerning the position.

Response to Arguments

The response traverses the rejection. The response asserts that the Examiner is essentially disregarding the Decision on Appeal with regard to the functional requirements recited. This argument has been reviewed but is not persuasive. The Decision on Appeal mailed September 27, 2005, specifically states that the "means for obtaining information concerning the positions of the probes" is a stimuable phosphor sheet. Shiraishi specifically teaches a stimuable phosphor sheet (see abstract).

With respect to the "means for attaching management information peculiar to the test piece to a predetermined location on the test piece using a marker the same as or similar to the marker used for marking the target substance" the specification specifically teaches that an ink jet and a spotter would be capable of attaching the

management information. The gel electrophoresis gel of Shiraishi would function to similarly place the management information to a predetermined location on the test piece, namely the gel. The electrophoretic nature allows nucleic acids, i.e. management information, to be placed on the gel at a predetermined location. Thus, the electrophoretic gel would constitute an equivalent of an ink jet or spotter specifically enumerated by the instant specification.

The response asserts that the claim requires attaching the management information to a predetermined location and the electrophoresis gel analysis depends on the location of a radioactive binding reaction. This argument has been thoroughly reviewed but not deemed persuasive because location of the management information is predetermined based upon the size and weight of the biological elements. The response asserts that the marker is also part of the functional recitation of the means for attaching. This argument has been reviewed but is not persuasive because the response does not specifically point to the specification for the means which are encompassed by the instant claims. The examiner has set forth analysis of why a gel electrophoresis would be encompassed by the instant claims, however the response relies neither on the specification nor any analysis have been provided which would suggest that a gel electrophoresis is not encompassed by the "means for attaching management information peculiar to the test piece to a predetermined location on the test piece using a marker the same as or similar to the marker used for marking the target substance."

Finally, the response asserts that the Shiraishi reference does not teach a marker for the management information. This argument has been thoroughly reviewed but not deemed persuasive because the claims are directed to a means for attaching management information. As provided above, the electrophoretic gel provides this function.

In view of the means plus function of the instant claims, the examiner has interpreted the various means as follow. Applicants are invited to provide specific arguments as to why the examiner's interpretation of the various means are not encompassed by the instant claims, relying on the specification or the art.

- "means for attaching management information peculiar to the test piece to a predetermined location on the test piece using a marker the same as or similar to the marker used for marking the target substance"
 - Spotter
 - Ink Jet
 - Gel electrophoresis
 - Pipette
- "means for obtaining information concerning the positions of the probes to which the target substance has bound and simultaneously detecting the management information attached to the test piece."
 - Stimulable phosphor sheet- as interpreted by the Decision on Appeal, September 27, 2005.
- "means for storing the management information in association with the information concerning the positions of the probes to which the target substance has bound.

- Computer
- Database
- Stimulable phosphor sheet
- Gel electrophoresis

Thus for the reasons above and those already of record, the rejection is maintained.

5. Claims 7-8, 10-11, 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuchiya et al. (US Pat. 5,672,514, September 30, 1997).

Given the clear decision by the Board of Appeals on September 27, 2005, the "means for obtaining information concerning the positions of the probes to which the target substance has bound and simultaneously detecting the management information attached to the test piece" has been defined by the decision and the specification as a "stimulable phosphor sheet" (see page 6 of the decision).

In *Re Donaldson*, 16 F.3d 1189, 1193, 29 USPQ2d 1845, 1848 (Fed. Cir. 1994), the court held: The plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure.

Tsuchiya teaches an analysis system comprising:

a) a means for attaching management information; namely a pipette which allows the dropping of solutions (col. 15, lines 48-55)

b) a means for obtaining information concerning the position of the probes, namely a stimuable phosphor sheet (col 17, lines 10-15)

c) means for storing the management information in association with the information concerning the positions of the probes to which the target substance has bound, namely a helium-neon laser beam using the image data reading apparatus shown in Figure 2 and the stimulated emission was photoelectrically detected and converted to digital signals. Tsuchiya teaches images were reproduced on the screen of the CRT based on the digital signals and the DNA could be detected (col. 17, lines 27-35). Tsuchiya teaches although information regarding chemiluminescence converted to digital signals is displayed as images on the screen of the CFT, it may be displayed on other display means or be reproduced on a recording media such as a photographic film (col. 19, lines 35-40).

Once the images are displayed on a screen, one may visually search through the images on the screen using their eyes (limitations of Claim 7, 10).

Response to Arguments

The response traverses the rejection. The response asserts that Tsuchiya is silent with regard to the attachment of management information. This argument has been considered but is not convincing because the analysis system of the instant claims is drawn to a product. The product of the instant claims is drawn to a means for attaching management information which encompasses a pipette.

The response asserts that for claims 7 and 10, the searching elements cannot be operations provided by a user in an apparatus claim. The response cites In re Bell, 26

USPQ2d 1529, however In re Bell is directed to genes and nucleic acids and does not contain the keywords apparatus or user in the body of the decision. Therefore, it is unclear as to the relevance of In re Bell.

The response further asserts that Hewlett-Packard Co. v. Mustek Systems Inc., 67 USPQ2d 1825 supports that the searching elements cannot be operations provided by a user in an apparatus claim. This argument has been thoroughly reviewed, but is not persuasive. The response cites to 1829-1830. At this portion of the decision, it is clear that the "user must select a scan speed", however the user in the accused method is selecting a resolution. The court does not appear to speak to whether the operations provided by a user can or cannot teach features of an apparatus claim as asserted by the response. It actually appears that the user can provide operations of an apparatus claim since the means plus function language provided in Hewlett-Packard is inferring user input. Thus, the reliance on Hewlett-Packard appears misplaced.

The claims 18 and 19 are asserted to more particularly describe the content of the management information. However, as discussed previously, the claims are drawn to a product which is a means for attaching management information. The means include

- Spotter
- Ink Jet
- Gel electrophoresis
- Pipette.

The apparatus of Tsuchiya includes a pipette which would serve the means of attaching the management information.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

6. **No claims allowable over the art.**

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Art Unit: 1634

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

A handwritten signature in black ink, appearing to read "J. Goldberg", is positioned above the printed name.

Jeanine Goldberg

Primary Examiner

November 27, 2006